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Medical Entrepreneurship and Generic Orphan Drug Production in India: A Legal Analysis

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Abstract

India is home to between 72 and 96 million persons living with rare diseases, yet it remains without a dedicated Orphan Drug Act and lacks the structured incentives, including market exclusivity, tax credits, and protocol assistance, that have catalysed orphan drug development in the United States and the European Union. This article examines how medical entrepreneurship, operating within the existing legal architecture of the Patents Act, 1970, the New Drugs and Clinical Trials Rules, 2019, and the National Policy for Rare Diseases, 2021, can accelerate the domestic production of generic orphan drugs in India. Using doctrinal legal analysis and a structured review of pharmaceutical entrepreneurship literature, the article identifies three operative legal pathways: patent challenge under Section 3(d), compulsory licensing under Section 84, and the CDSCO clinical trial waiver for orphan applications. The article further proposes a framework for targeted legislative reform to unlock generic orphan drug entrepreneurship at scale. © 2026 Forester Communications Inc.. All rights reserved.

Author keywords

CDSCO; Compulsory Licensing; Generic Pharmaceuticals; Indian Patent Law; Medical Entrepreneurship; NPRD 2021; Orphan Drugs; Rare Diseases; Section 3(d); TRIPS Flexibilities

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